



11-12-02

GPO/1642  
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Attorney's Docket No. 35784/209112 (5784-50)

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Caligiuri *et al.* Confirmation No.: 8842  
Appl. No.: 09/855,342 Group Art Unit: 1642  
Filed: May 14, 2001 Examiner: Stephen L. Rawlings  
For: METHODS OF THERAPY FOR CANCERS CHARACTERIZED BY  
OVEREXPRESSION OF HER2 RECEPTOR PROTEIN

Commissioner for Patents  
Washington, DC 20231

Sir:

Transmitted herewith is an AMENDMENT in the above-identified patent application.

Applicant claims small entity status. See 37 C.F.R. § 1.27.  
 No additional fee is required.

The fee has been calculated as shown below:

(COL. 1)		(COL. 2)	(COL. 3)	SMALL ENTITY		OTHER THAN A SMALL ENTITY	
CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDIT. FEE	OR RATE	ADDIT. FEE
TOTAL	* 39	** 21	= 18	X9=	\$	X18=	\$ 324
INDEP	* 4	*** 3	= 1	X42=	\$	X84=	\$ 84
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+140=	\$	+280=	\$
				TOTAL ADD FEE \$		OR TOTAL	\$ 408

\* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.

\*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space. The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Col. 1 of a prior Amendment or the number of claims originally filed.

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Atty. Dock. No. 35784/209112 (5784-50)  
Page 2

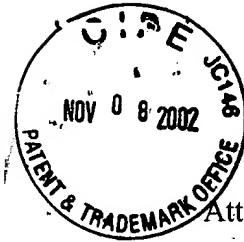
- Please charge my Deposit Account No. 16-0605 in the amount of \$
- A check in the amount \$408 to cover the additional fee is enclosed.
- The Commissioner is hereby authorized to charge any deficiency in payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 16-0605.
- Any additional filing fees required under 37 C.F.R. § 1.16 for the presentation of extra claims.
- Any patent application processing fees under 37 C.F.R. § 1.17.

Respectfully submitted,

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Attorney/Agent of Record

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<p><b>CUSTOMER NO. 00826</b> <b>ALSTON &amp; BIRD LLP</b> Bank of America Plaza 101 South Tryon Street, Suite 4000 Charlotte, NC 28280-4000 Tel Raleigh Office (919) 862-2200 Fax Raleigh Office (919) 862-2260</p>	<p>"Express Mail" mailing label number EL 868645730 US Date of Deposit November 8, 2002 I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner For Patents, Washington, DC 20231.</p> <p>Lynda-Jo Pixley</p>
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November 8, 2002

Commissioner for Patents  
Washington, DC 20231

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**PRELIMINARY AMENDMENT**

Prior to the substantive examination of the above-referenced application on its merits, the Examiner is respectfully requested to enter the following amendments.

In the Claims:

Please cancel claims 1-11 without prejudice to or disclaimer of the subject matter encompassed thereby.

Please amend claims 12, and 14-21 to read as follows:

*B1*

12. (Amended) A method of treating a cancer characterized by overexpression of the HER2 receptor protein in a subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or variant thereof, wherein said concurrent therapy comprises administering to said subject at least one therapeutically effective dose of IL-2 or variant thereof in combination with a dosing regimen for said anti-HER2 antibody or fragment thereof, wherein said dosing regimen for said anti-HER2 antibody or fragment thereof comprises administering to said subject at least one therapeutically effective dose of said anti-HER2 antibody or fragment thereof, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.5 mIU/m<sup>2</sup> to about 4.0 mIU/m<sup>2</sup>.

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324.00 DP

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02 FC:1202